

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION		APPLICATION FOR A VARIANCE FROM 21 CFR 1016.11(c) FOR A LASER LIGHT SHOW, DISPLAY, OR DEVICE		FORM NO. 1016-11(c) REV. 10/99 PL 02
NOTE: The laser light show, projector system, or device may vary from compliance with 21 CFR 1016.11(c) or design of use without the approval of the FDA.				
INSTRUCTIONS 1. Fill in your application to the Device Management Branch (DPA-205), Food and Drug Administration, Room 6-43, 5600 Fishers Lane, Rockville, MD 20857. Enter device number if stamped.				
1. NAME OF COMPANY Peppermill Casino		2. ADDRESS OF COMPANY (Include ZIP Code) (If P.O. Box is used, include actual street address also.) 2707 S Virginia St Reno Nevada 89502		
3. NAME AND TITLE OF RESPONSIBLE PERSON Giyo Gulli		4. TELEPHONE NO. (Include area code) (775) 836-2121		5. DATE OF SUBMISSION 10-28-99
6. THE APPLICANT REQUESTS THE VARIANCE TO BE IN EFFECT FOR A PERIOD OF 2 YEARS FROM THE DATE OF ISSUE. On expiry, the Agency will evaluate a variance for only two years. If a longer period is requested, it will be evaluated on a case-by-case basis.				
7. PRODUCT DESCRIPTION AND USE				
a. LIST NAME AND/OR MODEL NUMBER(S) FOR THE LASER LIGHT SHOW(S) AND PROJECTOR(S) LASERUM CSLP PROJECTOR MANUFACTURED BY LASER IMAGES, INC. (VARIANCE #78P-01)				
b. PRODUCT FOR WHICH A VARIANCE IS REQUESTED <input type="checkbox"/> A laser display device <input checked="" type="checkbox"/> A projector for a laser light show <input type="checkbox"/> A laser light show <input type="checkbox"/> Other (Specify) _____		c. PROJECTORS ARE INTENDED FOR SALE, LEASE, OR LOAN TO OTHER LASER LIGHT SHOW PRODUCERS <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
d. PRODUCT IS INTENDED FOR USE IN A <input checked="" type="checkbox"/> Performance or other dance projection theatre <input type="checkbox"/> Theater <input type="checkbox"/> Nightclub, ballroom or meeting room <input type="checkbox"/> Store displays <input type="checkbox"/> Trade show or convention <input type="checkbox"/> Displacement of night club <input type="checkbox"/> Pavilion <input type="checkbox"/> Indoor arena <input type="checkbox"/> Outdoor arena <input type="checkbox"/> Museum <input type="checkbox"/> Outdoor unenclosed area <input type="checkbox"/> Other (Specify) _____		e. PRODUCT IS INTENDED TO BE USED <input checked="" type="checkbox"/> At only one (1) location <input type="checkbox"/> At a variety of (How) locations (Specify) _____		
f. PRODUCT IS INTENDED TO BE USED AT ANY ONE LOCATION <input type="checkbox"/> More than 15 days <input checked="" type="checkbox"/> More than 5 but not more than 15 days <input type="checkbox"/> Less than 5 days		g. TOUR IS INTENDED TO RUN FOR <input type="checkbox"/> More than 6 months <input type="checkbox"/> 1-6 months <input type="checkbox"/> Less than one month <input type="checkbox"/> Not applicable (Not a tour) <input type="checkbox"/> Other (Specify) _____		
h. PRODUCT UTILIZES THE FOLLOWING LASER EFFECTS <input checked="" type="checkbox"/> Front projection <input type="checkbox"/> Rear screen projection <input type="checkbox"/> Holographic displays <input type="checkbox"/> Multiple reflection/diffraction effects <input type="checkbox"/> Audience scanning (Also includes scanning any accessible unenclosed areas) <input type="checkbox"/> Reflections from temporary mirrors or mirrored surfaces (Beam Mirrors) <input type="checkbox"/> Stationary irradiation of rotating mirror balls, etc. <input type="checkbox"/> Scanning irradiation of rotating mirror balls, etc. <input type="checkbox"/> Fiber optic projections <input type="checkbox"/> Fog, smoke, or other scattering substances effects <input type="checkbox"/> Other (Specify) _____				
8. LASER RADIATION LEVELS				
LASER MEDIA (21 CFR 101.11) KRYPTON ARGON MIXED		WAVE LENGTHS (nm) 457 - 676 nm		BEAM POWER (watts) 4 WATTS
9. IF ANY LASER RADIATION IS PULSED OR SCANNED, GIVE THE PULSE DURATION AND RATE AND SCANNING FREQUENCY AND AMPLITUDE AVERAGE SCAN RATE IS 30,000 POINTS PER SECOND AT 80° MAXIMUM DEPLETION.				
10. REASON FOR REQUESTING VARIANCE <input checked="" type="checkbox"/> Compliance with the intent of 21 CFR 1016.11(c) would require the intended use of the product because compliance would have the same effect to the extent that the desired effect could not be sufficiently realized. <input type="checkbox"/> Other or additional explanation (Specify) _____				

11. EXPLAIN HOW YOUR PRODUCT IS DESIGNED TO DEVIATE FROM THE REQUIREMENTS OF THE APPLICABLE STANDARDS

- It is designed to deviate from the provisions of 21 CFR 1048.11(c) in that the scientific evidence base would exceed the scientific evidence base specified in 21 CFR 1048.11(c).
- It is designed to deviate from the provisions of 21 CFR 1048.11(c) as follows:

12. ADVANTAGES TO BE DERIVED FROM SUCH DEVIATION

- Laser light shows and displays are accepted popular forms of entertainment and the safe use of laser light in cases of the kind intended by 21 CFR 1048.11(c) is necessary to achieve the required effects of these shows.
- Other or additional advantages (specify and explain)

13. EXPLAIN THE ALTERNATE MEANS OF RADIATION PROTECTION TO BE PROVIDED (Check in every space as applicable. Do not use "Remarks" justify items not checked. Justify additional items as necessary. Make any other means of radiation protection that will be used.)

- All laser projects, systems, shows and projections will be carried in compliance with 21 CFR 1048.10 and the conditions of the variance and be reported as required by 21 CFR 1048.18 and 1048.17 using the reporting forms provided for laser projects. These reports will be accomplished prior to any performance with the variance.
- Effects not specifically indicated in this variance application will not be performed. No other effects will be added until an amendment to the variance has been obtained and the required reports or approvals, as applicable, have been submitted.
- Scanning, projection, or reflection of laser and collimated radiation (light show) shall not be performed or other applicable restricted areas will not be permitted except for diffuse reflections produced by the atmosphere, added atmospheric scattering media, and target screens.
- Laser radiation levels in excess of the limits of Class I will not be permitted at any point less than 3.9 meters above any surface upon which persons other than operators, performers, or employees are permitted to stand or 2.5 meters below or in lateral projection from any place where such persons are permitted to be. Operators, performers, and employees will not be required or allowed to wear radiation protective headsets of Class I or be required to radiation above the levels specified in 21 CFR 1048.11(c).
- Any product which relies on scanning to meet access, egress, or product class limits will incorporate a scanning safeguard system which directly senses viewer motion and which will react fast enough to provide exceeding the applicable limit.
- All laser light shows shall be under the direct and personal control of trained, competent operator(s). The operator(s) will:
 - (1) Immediately terminate the emission of light when a violation in the event of any unsafe condition.
 - (2) Be located where all beam paths can be directly observed at all times and
 - (3) Be an employee of the variance holder who will be responsible for the training and the conduct of the operator.
- The maximum laser projection power will not exceed the level required to obtain the intended effects.
- The projection system (i.e., the projector and all other components used to produce the light) will be securely mounted or anchored and to prevent unintended movement or misalignment. Beam marking will be provided when necessary part of the system design to prevent obscuring of screens, beam stops, targets, etc.
- Laser projectors will not be delivered to any other party until an agreement of sale form, signed and dated the recipient demonstrates that they have a variance in effect at the time of delivery that permits them to produce laser light shows complying with 21 CFR 1048.11.
- In addition to the requirements of 21 CFR 1048.15(h), the manufacturer of laser projector systems will provide to persons who purchase, lease, or borrow the equipment, adequate user instructions for safe installation and operation which specify the responsibility of the recipient as an independent light show manufacturer to submit the required reports and apply for and obtain a variance from 21 CFR 1048.11(c) and to terminate all operations of any laser light show.
- The requirements of 21 CFR 1048.20(a)(1) and (2) will be accomplished through the use of written procedures for visual alignment, laser and performance of each show. These procedures will be sufficient detail to ensure compliance with 21 CFR 1048.10, the conditions of the variance, and the control of access to the laser area using the standards described in the ANSI Z39.1 standard for the safe use of lasers (American National Standards Institute, 1430 Broadway, New York, NY 10018) or any other equivalent laser commission standard and, when applicable, state or local regulations. Laser radiation areas which are common to all laser shows shall be clearly marked in 21 CFR 1048.11(c) and be clearly identified by the posting of warning signs and restricting access through physical means such as barriers, notices, signs, etc. These requirements apply to temporary areas such as shows and up and down permanent areas and to fixed or permanent areas. The variance holder will retain the record of these procedures and the results of all tests as required by 21 CFR 1048.17. A copy of the variance application, the approval letter, current procedures, and records relating to each projector show will with the operator or other responsible individual and will be made available for inspection by FDA and other responsible individuals.

- (1) The Center for Devices and Radiological Health, Office of Compliance and Surveillance (CDR-310), 1700 Donald Drive, Rockville, MD 20850 providing the proposal and design data for fixed installations and the necessary for mobile systems. In addition, copies of each of the above have been reported and reviewed in order to clearly understand, each reader will identify specific descriptions of each show and a listing of effects to be performed in sufficient detail to conform compliance with the regulations and CDH standards.
- (2) The Federal Aviation Administration (FAA) for any operations with open airspace of any kind (i.e., including but not limited to, operations, operations, etc.). If the FAA objects to any such effects, the objections will be resolved and any conditions requested by FAA will be adhered to. If there are no objections, the objections by effects will be deleted from the plan.
- (3) Some may have to be done under special circumstances by all shows to be performed under their jurisdiction. All requirements of state and local laws will be satisfied and any objections raised by local jurisdiction will be resolved or the effects deleted. (A list of Federal and state offices is available from the Center for Devices and Radiological Health website.)

14. REMARKS

The projector is to be permanently installed in the Italian Restaurant of the Peppermill Hotel Casino and will project an automated sequence of Lucia (interference patterns) and scanned imagery on the domed ceiling. The projector will be mounted over 4 meters above and out of the site line of the audience. The front projection surface will be an additional 4 meters above the projector.

The operator shall inspect the installation prior to starting the daily sequences to insure compliance and overall safety. There will be a training program to make the operator and staff aware of safe operation practices. Continuous monitoring shall be achieved by a combination of video surveillance and the restaurant staff, all with access to emergency stop buttons. Communications between the restaurant and the designated operator will also be provided.

SIGNATURE

I CERTIFY that all of the above information and statements are true, complete, and correct to the best of my knowledge and understanding and my signature application may be denied or my variance may be revoked if the application is found to be false, misleading, or incomplete in any material way. I have submitted and will submit all reports required by 21 CFR 1002.10 and 1002.12 on the laser equipment and show(s). I further understand that I may be required by regulation or by the Director, Center for Devices and Radiological Health, to supply such other information as may be necessary to evaluate and act on this application.

15. SIGNATURE

Quino Galli

16. NAME (Print or Stamp)

Quino Galli

17. TITLE

Special Effects Mgr